

K972410 IMPERVIOUS ISOLATION GOWNSep 19, 1997
85 days to decisionK972410 · Product code: **FYC** · General HospitalSource: <https://www.510kdatabase.net/k972410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Jun 26, 1997
Decision date	Sep 19, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kentron Health Care, Inc.
Location	Hollywood, FL, US
Contact	NARI SADARANGANI
510(k) history	6 submissions · 6 cleared · 1995-2003

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